UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,469	10/20/2003	Patrice Debregeas	065691-0339	4165

22428 7590 03/08/2007
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
HUYNH, CARLIC K	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/689,469	DEBREGEAS ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/312,485.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :24 November 2003, 08 November 2004, and 12 September 2005..

DETAILED ACTION

Status of the Claims

1. Claims 1-12 are pending in the application in response to the restriction requirement submitted on November 3, 2006. Accordingly, claims 1-12 are being examined on the merits herein.

Election/Restrictions

2. Applicants' election of the species of mannitol and Gingko biloba in the reply filed on December 4, 2006 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The election/restriction requirement is deemed proper and is made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on November 24, 2003, November 8, 2004, and September 12, 2005 is acknowledged.

Specification

3. The use of the trademark Eudragit®, Eudragit NE 30D®, and Eudragit E 100® has been noted in this application (page 7, paragraphs [0026]-[0027]). It should be capitalized wherever it appears and be accompanied by the generic terminology.

The use of the trademark Aquacoat® has been noted in this application (page 7, paragraph [0026]). It should be capitalized wherever it appears and be accompanied by the generic terminology.

The use of the trademark Pharmacoat® has been noted in this application (page 7, paragraph [0027]). It should be capitalized wherever it appears and be accompanied by the generic terminology.

The use of the trademark PVP K30® has been noted in this application (page 11, paragraph [0052]; page 11, paragraph [0054]; page 12, example 2; page 13, example 4; and page 14, example 5). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

4. Claim 9 is objected to because of the following informalities: typographical error. "Ginkgo biloba" and "Harpagophytum" are spelled incorrectly in the instant claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menzi et al. (6,056,949), in view of Nissenson et al. (The Western Journal of Medicine, 1979, 131, pp. 277-284), Debregeas et al. (4,960,596), De Long et al. (6,030,621) and DeBregeas et al. (U.S. Patent 6,228,395).

Menzi et al. teach flavorant or odorant granules of natural (vegetable or animal) or synthetic origin with a particle size of 20 to 3000 μm in diameter (column 2, lines 9-10 and lines 60-61). The granules can be used with carbohydrates, e.g. sugars or chemically modified starches such as sucrose (column 2, lines 11-12 and 22-23).

Menzi et al. also teach that the particles can be coated after granulation by spraying a solution of polyvinylpyrrolidone (column 2, lines 40-47). The coated particles may contain other pharmaceutically acceptable excipients such as dyes, vitamins, etc. (column 2, lines 35-36).

Menzi et al. teach that such granules are used as flavorants and odorants (column 2, line 57).

Menzi et al. do not teach the neutral core having a starch/sucrose core in a 20/80 mass ratio, which is coated with 80% by weight of starch.

Menzi et al. also do not teach the controlled or delay release from the granule, or granules containing ethylcellulose with a plasticizer or hydroxypropylmethylcellulose.

Menzi et al. also do not teach the plant substance, the weight of the plant substance to the total weight of the granule, or the granule having multiple layers.

Although Menzi et al. do not teach mannitol specifically, Nissenson et al., teach mannitol is made from the carbohydrate, or sugar, dextrose (p. 277). Mannitol is a modified sugar and as such, it is reasonably expected that a composition of any sugar, e.g. sucrose from the composition of Menzi et al., would yield the same composition comprising a sugar substance as recited in the instant claim 2.

Although Menzi et al. do not teach granules made from Gingko biloba extracts specifically, De Long et al. teach granules made from Ginkgo biloba extracts and that the weight of such extracts account for 4% of the total weight of the granule (abstract and column 16. lines 55-65).

Debregeas et al. teach granules that are coated with ethylcellulose and capable of a controlled release of Diltiazem (column 4, lines 4-10).

DeBregeas et al. teach bi-layered granules capable of rapid release and granules capable of slow release (column 2, lines 10-24). These granules are coated with hydroxypropylmethylcellulose and contain a plasticizer and a binder (column 2, line 50; column 3, lines 30-31; and column 4, lines 20-24).

DeBregeas et al. also teach a starch/sugar weight ratio in the region of 75/25, with the starch accounting for 75% by weight (column 3, lines 11-12).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the granule composition of Menzi et al. to contain Ginkgo biloba extract, to be coated with ethylcellulose as to allow for controlled release, to be coated with hydroxypropylmethylcellulose as to allow for slow release, and to contain a sugar because the granules of De Long et al. contain Ginkgo biloba extracts, the granules of Debregeas et al.

contain ethylcellulose which allows for controlled release, the granules of DeBregeas et al. contain hydroxypropylmethylcellulose which allows for slow release, and the composition of Nissenson et al. contain mannitol which is a modified sugar and according to De Long et al., Debregeas et al., and DeBregeas et al., the granules contain Ginkgo biloba extracts and according to Nissenson et al., mannitol is a modified sugar.

The motivation to combine the granule composition of Menzi et al. to the granules of De Long et al., Debregeas et al., and DeBregeas et al. as well as the mannitol of Nissenson et al. is that the granules of De Long et al. contain Ginkgo biloba extracts, the granules of Debregeas et al. contain ethylcellulose which allows for controlled release, the granules of DeBregeas et al. contain hydroxypropylmethylcellulose which allows for slow release, and the composition of Nissenson et al. contain mannitol which is a modified sugar.

Regarding the mass ratio of the starch/sucrose core and the weight of the starch as recited in the instant claim 3, it is noted that DeBregeas et al. teach the mass ratio of starch/sucrose in the region of 75/25 and the starch content at 75%, which closely meets the mass ratio of starch/sucrose and the starch content set forth in instant claim 3. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of chromium picolinate provided in a composition, according to the guidance set forth in Boynton et al., to provide a composition having desired chromium content. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the content of the plant substance as recited in instant claim 10, it is noted that between 0.1 mg/g and 750 mg/g weight of plant substance to the total weight of the granule is equivalent to 0.01% to 75% by weight of plant substance in the granule.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1 and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of Debregeas et al. (5,385,739), claim 21 of Leduc et al. (5,549,911), claims 13 and 21 of Debregeas et al. (6,077,544), claims 17, 25, and 26 of Debregeas et al. (6,139,877), claims 17, 25, and 26 of Debregeas et al. (6,458,389), claim 10 of Debregeas et al. (6,482,437), claim 14 of Debregeas et al. (6,551,621), and claim 1 of Debregeas et al. (6,770,298). Although the conflicting claims are not identical, they are not patentably

distinct from each other because the above claims of each of the Debregeas et al. patents and claim 21 of Leduc et al. are directed at granules, which is the same granules used in granules in the instant claims 1 and 12. Thus the granules are not patentably distinct between each of the Debregeas et al. patents and the instant application.

7. Claims 1 and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of Debregeas et al. (4,960,596), claims 1, 10, and 18 of Debregeas et al. (Re. 35,903), claim 1 of Debregeas et al. (5,385,739), claim 1 of Leduc et al. (5,549,911), claim 1 of Debregeas et al. (6,077,544), claim 1 of Debregeas et al. (6,139,877), claim 1 of DeBregeas et al. (6,228,395), claim 1 of Debregeas et al. (6,383,516), claim 1 of Debregeas et al. (6,458,389), claim 1 of Debregeas et al. (6,482,437), claim 1 of Debregeas et al. (6,551,621), and claim 1 of Debregeas et al. (6,660,296) in view of Menzi et al. (6,056,949), Nissenson et al. (The Western Journal of Medicine, 1979, 131, pp. 277-284), Debregeas et al. (4,960,596), De Long et al. (6,030,621) and DeBregeas et al. (U.S. Patent 6,228,395) as applied to claims 1-12 above.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

CHENGJUN WA